

Remarks

In the outstanding Office Action, the Examiner:

(1) rejected claims 1-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement;

(2) rejected claims 1, 2 and 4 under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,026,379) ("Yoon '379") in view of Yoon (5,226,426) ("Yoon '426"); and

(3) rejected claim 3 under 35 U.S.C. 103(a) as being unpatentable over Yoon ('379) in view of Yoon ('426) and further in view of Hasson (4,174,715) ("Hasson").

In response, Applicant has now canceled claim 3 and amended claims 1 and 4 to more clearly define the present invention and to further distinguish the present invention from the prior art.

More particularly, in response to Item (1) above, Applicant has amended claims 1 and 4 to remove the language indicating that the second wire-like element defines a guide means for guiding the thin cord-like object into engagement with the hook-shaped distal end of the first wire-like element. Applicant has also added additional language that is believed to more clearly define the present invention as disclosed in the original specification.

In response to Item (2) above, Applicant respectfully disagrees with the Examiner's rejection of claims 1, 2 and 4 as being unpatentable over Yoon '379 and Yoon '426.

The patent to Yoon '379 discloses a surgical device which is useful for performing various medical procedures. Examples of such medical procedures include applying a flexible ligature to a tubular organ structure, introducing a gas into the surgical field and cutting and cauterizing the ends of a tubular structure. The surgical device comprises inner, middle and outer elongated tubular members 12, 14 and 16, respectively, wherein

the inner tubular member is slidably received within the middle tubular member and the middle tubular member is slidably received within the outer tubular member. The device further comprises forceps 30 attached to the distal end of the inner tubular member which extend from and retract into the distal end of the middle member by moving a handle 32 to slide inner tubular member within the middle tubular member.

Amended claim 1 of the present invention discloses a device comprising a hollow shaft with a pointed distal end, a lumen and a proximal end, a solid rod positioned in the lumen of the shaft in reciprocally sliding relationship therewith, first and second wire-like elements attached to the rod and preferably used to grasp thin cord-like objects and actuation means for moving the rod and wire-like elements between a first position and a second position so that the wire-like elements can grasp and carry a thin cord-like object. Furthermore, the actuation means comprises a housing, a trigger and a spring-biased piston.

The invention disclosed in Yoon '379 is significantly different than the device of the present invention.

First, the device in Yoon '379 utilizes three different members, inner, middle and outer, with the inner slidably received within the middle member and the middle member slidably received within the outer member. In contrast, the present invention is an improved device which comprises a hollow shaft and a rod with first and second wire-like elements attached to the rod for grasping a thin-cord like structure.

Second, the device in Yoon '379 uses a handle to slide the inner tubular member and the forceps within the tubular member. In contrast, the present invention uses an actuation device comprising a housing attached to the proximal end of the shaft, a trigger pivotally attached to the housing and a spring-biased

piston attached to the proximal end of the rod and configured to slide within the housing so as to move the rod (and thus the wire-like elements) between the first and second positions.

Third, and as stated by the Examiner, the device in Yoon '379 fails to show the distal end of the shaft as being pointed. This is significantly different than the present invention wherein the device has a shaft with a pointed distal end so that the device can force its way through soft tissue.

Furthermore, amended claim 4 discloses a method for grasping a suture at a surgical site and then passing it back and forth through a soft tissue. The method comprises providing the device of the present invention, positioning the rod with the wire-like elements in the first position, forcing the distal end of the shaft through soft tissue and maneuvering the distal end of the shaft so that it is adjacent to the suture, positioning the rod and the wire-like elements in the second position and in doing so trapping the suture and carrying it back toward and into the distal end of the shaft and further maneuvering the device between the first and second positions so that it can pass the suture back and forth through the soft tissue.

Each of the differences between the invention disclosed in Yoon '379 and the present invention provide significant improvements over Yoon '379 by providing a device and method useful for grasping a suture at a surgical site and then passing it back and forth through a soft tissue. More specifically, using the device of Yoon '379 to grasp a suture and pass it back and forth through a soft tissue would require the insertion of an additional instrument (such as a needle or a cannula) through the inner tubular member and into the surgical field. The need to use multiple instruments complicates procedures, particularly during closed surgical settings. In contrast, the present

invention provides a device and a method which enables the user to pierce soft tissue prior to grasping a length of suture and then pass the suture through the soft tissue as the device is pulled back through the soft tissue, without interference from the wire-like elements, and solely with the use of one instrument. The device of Yoon '379 does not allow a user to perform these maneuvers with the use of only one instrument.

Furthermore, the present invention is not rendered obvious by the combination of Yoon '379 with Yoon '426.

Yoon '426 discloses a safety penetrating instrument including an elongate, tubular needle 32, a safety probe 34 movably disposed concentrically within the needle, an elongate, tubular portal sleeve 36 concentrically disposed around the needle, a hub and a housing. The hub mounts the needle and the safety probe and the housing mounts the portal sleeve so that the safety penetrating instrument is made up of two separate units (1) a portal unit which includes the portal sleeve and housing and (2) a penetrating unit which includes the needle, safety probe and hub.

Yoon's device provides a needle for penetrating tissue but Yoon '426 does not disclose a device or a method useful for grasping a suture at a surgical site and then passing it back and forth through a soft tissue. Even with the combination of Yoon '379 and Yoon '426 it would still be necessary to utilize more than one instrument to perform the maneuvers that the device of the present invention is capable of.

With regard to the Examiner's indication that opposing parts 132 and 134 could be used as grasping means similar to the wire-like elements of the present invention, Applicant respectfully disagrees. Yoon '426 discloses a sharp, tissue penetrating tip on a needle wherein the distal end of the safety probe, which is

used to protect the needle, is split or slotted to form opposing parts 132 and 134. The opposing parts form large blunt linear grasping elements which are clearly not wire-like and are therefore not suitable for grasping thin-cord like objects, as required by the claims of the present patent application. The intention with both Yoon '379 and Yoon '426 is to grasp and/or cut tissue and not for grasping a suture at a surgical site and passing it back and forth through a soft tissue.

Accordingly, it is submitted that the rejection of claims 1, 2 and 4 over the combination of Yoon '379 with Yoon '426 is untenable since the combined references still fail to render the claimed invention obvious.

In response to Item 3 above, Applicants respectfully disagree that the present invention is rendered obvious by the combination of Yoon '379, Yoon '426 and Hasson.

As stated above, the actuation means of the present invention enables the user to move the rod and wire-like elements between the first position and the second position so that the wire-like elements can grasp and carry a thin-cord like object. The actuation means comprises a housing attached to the proximal end of the shaft, a trigger pivotally attached to the housing and a spring biased piston attached to the proximal end of the rod and configured to slide within the housing so as to move the rod between the first and second positions. The rod of the present invention normally resides within the shaft, however, upon engagement of the trigger the piston moves distally against the force of the spring and the rod extends out of the shaft.

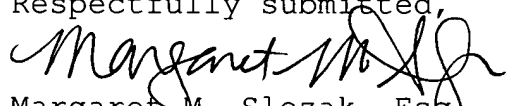
There is nothing in Yoon '379, Yoon '426 or Hasson which teaches using the actuation means of the present invention. Yoon '379 use a handle to slide a tubular member (and thus the forceps) within an outer tubular member. Yoon '426 uses a

spring, pin and slot configuration to move the safety probe. Hasson uses a spring with a thumb-operated actuator which compresses the spring and moves the outermost sleeve from a rearward position to a forward position. Hasson, however, does not teach using actuation means wherein engagement of a trigger, which is pivotally attached to a housing, moves a piston distally against the force of the spring to extend the rod out of the shaft.

Accordingly, the present invention is not believed to be rendered obvious by the combination of Yoon '379, Yoon '426 and Hasson. Therefore, this application is believed to be in condition for allowance and allowance thereof is respectfully requested.

In the event that any additional fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

Margaret M. Slezak, Esq.
Registration No. 55,625
Pandiscio & Pandiscio, P.C.
470 Totten Pond Road
Waltham, MA 02451-1914
Tel. No.: (781) 290-0060